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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,314	11/20/2001	James P Burnie	P0281578	2305

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,314	BURNIE ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- Th MAILING DATE of this communication appears on th cov r she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2,3,5-7 and 9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,8 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response to restriction in Paper No. 10 (1/15/03) is acknowledged. Claims 1-14 are pending in the application.

Election

2. Applicant's election Group I, claims 1, 4-5, 8 and 14 with respect to SEQID.NO: 2 without traverse in Paper # 10 is acknowledged. Claims 2-3, 6-7 and 9-13 have been withdrawn from consideration, drawn to non-elected invention. Claim 5 is withdrawn from elected invention, as claim 5 does not recite the elected SEQID.NO: 2. Claims 1, 4, 8 and 14 are under examination.

Priority

3. This application 371 is a national stage entry of PCT/GB00/00237, 1/28/2000 which claims priority under 35, U.S.C. 119 (a)- (d) to UNITED KINGDOM 9902555.3, 02/05/1999 Is acknowledged. Claims 1, 4, 8 and 14 with respect SEQ.ID.NO: 2 are accorded priority as of 12/7/1998.

Information Disclosure Statement

4. The Information Disclosure Statement has not been filed in this application.

Specification - Informalities

5. Claims should begin with "I claim" or "'we claim" or "What is claimed is".

It is noted that Abstract of the Disclosure is missing. If applicant desires to include the abstract from PCT/GB00/00237, 1/28/2000, a copy of the abstract will be inserted in to the specification. There are no line numbers in the specification pages. Title of the invention is not descriptive to the claimed invention. Applicant is advised to amend the title to recite the claimed invention, C.pneumoniae polypeptides in the treatment of Chlamydial infection.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, a C.pneumoniae protein as claimed, has the same characteristics as that found in nature because the protein can be obtained from any source such as human body etc. To overcome this rejection the Examiner suggests the amendment of the claims to include the terminology " isolated" or "purified". For relevant case law see *Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).*

Claim Rejections - 35 USC 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim is drawn to a method of treatment of infection due to C.pneumoniae comprising the step of administration to a patient a medicament comprising a protein, immunogenic fragments thereof, nucleotide sequence encoding same or an inhibitor thereof (Examiner is viewing the protein as SEQ.ID.NO: 2 and immunogenic fragments as fragments of SEQ.ID.NO: 2.

Instant claims are evaluated for enablement using Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a method of treatment comprising a protein or fragments thereof to t treat Chlamydia infection. The instant specification does not teach how to use the composition, without undue experimentation, for the treatment in the animal to which the substance is administered.

The specification discloses that the polypeptide of the instant claim is made and used in invitro neutralization assays.

It is noted that the specification, in pages 8-15 provides description of a C.pneumoniae 51 KD protein, epitopes of said protein that are used in invitro neutralization assays. However, the specification fails to teach a method of treatment of infection using the claimed protein or its

fragments. The specification does not provide how would an artisan have used the protein (by sequence identifier number) and its fragments to treat the infection against C.pneumoniae. Furthermore, just because the claimed polypeptide has neutralizing activity in an in vitro assay, the specifications does not ensure that the polypeptide or its fragments would be able to successfully treat an infected individual because the state of the art suggests possible protective role for antibodies in Chlamydia infections (see abstract and discussion of Ahmad et al 1997). Further, the specification provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo method* of using the claimed polypeptide or fragments thereof. However, it is unclear whether this approach is feasible in the treatment of Chlamydial infections using the claimed composition because the target antigen, an isolated polypeptide SEQ.ID.NO: 2 has not been shown to treat an ongoing infection in any animal model. Thus, an isolated polypeptide, SEQ.ID.NO: 2 as a pharmaceutical composition in the treatment of infection must be considered highly unpredictable, requiring a specific demonstration of efficacy of the polypeptide. Absent such demonstration, the invention would require undue experimentation to practice the claimed invention. Therefore, it is unpredictable that immunization of the claimed proteins would be able to treat an ongoing infection. It is concluded that the specification as filed is not enabling for the claimed invention as filed and an artisan would not have been able to practice the invention without undue experimentation.

Claim Rejections - 35 USC 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1, 4, 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as being vague and not clear for the recitation of " for use in a method of treatment or diagnosis of the human or animal body". Applicant is advised to amend the claim to recite "an isolated C.pneumoniae protein comprising the amino acid sequence as set forth in SEQ.ID.NO: 2, for the treatment or diagnosis of human or animal Chlamydial infection ".

Claim 4 provides for the use of treatment of infection, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicant is advised to amend the claim 4 to depend from claim1 since claims 2-3 are drawn to non-elected invention.

Claim 8 is rejected as being vague and not clear for the recitation of "a method of manufacture of a medicament for the treatment of infection by C.pneumoniae characterized in the use of protein, immunogenic fragment thereof or nucleotide sequence encoding same". Does the claim mean to recite, " a method of manufacturing the protein or immunogenic fragment thereof comprising---."

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, See MPEP. § 2172.01. The claim recites a method of manufacture of a medicament for the treatment of infection by C.pneumoniae. However, there are no steps, which indicate how the protein is manufactured.

Applicant is advised to amend the claim 14 to depend from claim 4only since claims 5-7 are drawn to non-elected invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, See MPEP. § 2172.01. There is no step, which correlates the treatment and administration of the protein.

Applicant is advised to amend the claims to recite only SEQ.ID.NO: 2 since this is an elected invention.

Claim Rejections - 35 USC 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1,4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Izutsu et al U.S.Patent 6,165,478.

Claims are directed to a C.pneumoniae protein having the amino acid sequence of SEQ.ID.NO: 2 or immunogenic fragment thereof or nucleotide sequence encoding it for use in a method of treatment or diagnosis of the human or animal body. Claims are also drawn to method of manufacture said protein.

Hiroshi Izutsu et al disclose a C.pneumoniae protein having the amino acid sequence of SEQ.ID.NO: 2 (see sequence alignment of the claimed protein SEQ.ID.NO: 2 with SEQ.ID.NO: 1 and 15 of the prior art and claims of the U.S.Patent 6,165,478). The disclosed prior art protein is 98.2% identical with SEQ.ID.NO: 2. The prior art also discloses the fragments of said protein (see the see sequence alignment of the claimed protein SEQ.ID.NO: 2 with SEQ.ID.NO: 5, 2 and 16 of the prior art) SEQ.ID.NO: 2. The disclosed protein fragments consist of 259 amino acids of said SEQ.ID.NO: 2. Further, the prior art teaches manufacturing said proteins by recombinant DNA technology (examples 3, 4 and 10). The prior art anticipated the claimed invention.

11. Claims 1, 4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Izutsu et al Accession Numbers E16639 and 16674 (JP1998210978).

The claims have been discussed supra.

Accession Numbers E16639 and 16674 disclose a C.pneumoniae protein encoded by DNA or fragments or nucleotide sequences encoding the protein having the amino acid sequence of SEQ.ID.NO: 2 (see sequence alignment of the claimed protein SEQ.ID.NO: 2 with the prior art protein sequence). The disclosed prior art protein is 99.5% identical with SEQ.ID.NO: 2. Further, the prior art teaches manufacturing said proteins by recombinant DNA technology (see the attached highlighted E.16639 and 16674). The prior art anticipated the claimed invention.

12. Claims 1, 4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Izutsu et al Accession Numbers AAR94584, AAR94579, AAR94586 or AAWO 1743.

The claims have been discussed supra.

Accession Numbers AAR 94584, AAR 94579, AAR 94586 and AAWO 1743 disclose a C.pneumoniae protein having the amino acid sequence of SEQ.ID.NO: 2 or fragments (see

sequence alignment of the claimed protein SEQ.ID.NO: 2 with the prior art protein sequences). The disclosed prior art protein AAR94584 is 77.8% identical with SEQ.ID.NO: 2 and read on the protein having the amino acid sequence of SEQ.ID.NO: 2. The disclosed prior art protein AAR 94579 is 57.5% identical with SEQ.ID.NO: 2. The disclosed prior art proteins AAR 94586 and AAWO 1743 are 52.2% identical with SEQ.ID.NO: 2. The disclosed AAR 94579, AAR 94586 and AAWO 1743 proteins read on the claimed fragments. Further, the prior art teaches manufacturing said proteins by recombinant DNA technology (see the highlighted abstracts of these accession numbers). The prior art anticipated the claimed invention.

Status of Claims

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

2/1/03

LYNETTE R. F. SMITH
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